



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,221	02/16/2001	Doris Hubler	JENA 3	7076

23599 7590 05/05/2004

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

09/719221

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
--------------------	-------------	-----------------------	------------------

EXAMINER

ART UNIT	PAPER NUMBER
----------	--------------

4/4/02

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 1/20/02

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-5, 7-28 is/are pending in the application.
☐ Of the above, claim(s) 3, 7-11, 14, 18, 19, 21-28 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1, 2, 4, 12, 13, 15, 16 is/are rejected.
☒ Claim(s) 20 is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 12, 13, 15, 16, 18, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hesch et al in view of Shealy et al and Riley et al.

Hesch et al. disclose that it is well-known in the art that androgens such as testosterone are useful in methods of treating androgen deficiency in man (column 1, lines 10-16). Such a deficiency is known to cause benign enlargements of the prostate (column 1, lines 46-54). Testosterone propionate is specified (column 1 line 13).

Shealy et al teach that it is known in the art to treat prostatic hypertrophy with DHEA (column 1 lines 43-49). Shealy et al increase serum DHEA level by a treatment comprising administration of progesterone (column 3 lines 63-67).

It would have been obvious to one of ordinary skill to add DHEA to the androgen deficiency treatment disclosed by Hesch et al to achieve the beneficial effect of treating the accompanying enlargement of the prostate in view of Shealy et al and further to add progesterone to the treatment to increase serum DHEA levels for the beneficial effect of further improving said prostate treatment, also in view of Shealy et al.

As to the claimed ranges of androgen and gestagen dosages, it is within the skill in the art to select optimal parameters such as ratios, ranges of doses or weight percents of components in order to achieve a beneficial effect. See In re Boesch, 205 USPQ 215 (CCPA 19880). Therefore, the ratios, ranges of doses or weight percents

Art Unit: 1617

instantly claimed are not considered critical absent evidence showing unexpected and superior results.

As to the claimed dosage forms of androgens and gestagens, Riley et al. disclose varieties of dosage forms for androgens and gestagens. It would have been obvious to one having ordinary skill in the art to choose a particular dosage form appropriate for the patient under treatment.

Claims 1, 2, 4, 12, 13, 15, 16, 18, 19 are rejected.


Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claims allowed.

Any inquiry concerning this communication should be directed to Edward J. Webman at telephone number 571-272-0633.

Webman/tgd

April 6, 2004


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500